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09/847,081	05/02/2001	Marco Busch	Mo-6314/LeA 34,326	7196

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,081	BUSCH ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-15,19,29-32,35,36 and 38-76* is/are pending in the application.

4a) Of the above claim(s) *1-6,8-15,19,29-32,35,36 and 58-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-44,51 and 55-57* is/are rejected.

7)☒ Claim(s) *45-50 and 52-54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *alignment* .

DETAILED ACTION

Status of the Application

Claims 1-6, 8-15, 19, 29-32, 35-36, 38-76 are pending.

It is noted that the examination of the instant application has been assigned to a different Examiner in Group Art Unit 1652.

Applicant's amendment of claim 35, cancellation of claims 7, 16-18, 20-21, 25-28, 33-34, 37, and addition of claims 39-76 in Paper No. 17, filed on 3/10/2003 is acknowledged.

Applicants elected without traverse Group VIII, claims 20-21, 33 and 34, drawn to a method of chemical screening, in Paper No.14, filed on 10/7/2002.

In response to a supplemental restriction submitted in Paper No. 15, mailed on 12/2/2002, Applicants have further elected to prosecute new claims 39-57. Since newly added claims 39-57 are drawn to the polynucleotide of SEQ ID NO: 1 or to a polynucleotide encoding the polypeptide of SEQ ID NO: 2, a method of producing the polypeptide of SEQ ID NO: 2, as well as host cells, vectors and plants comprising said polynucleotides, it appears that Applicants have elected to prosecute Group I as set forth in Paper No. 15, which is drawn to the nucleic acid of SEQ ID NO: 1, a nucleic acid encoding the polypeptide of SEQ ID NO: 2, and a method of generating a polypeptide. As such, the present Examiner will examine claim 38 and newly added claims 39-57 as drawn to the elected invention. It is noted that claim 19 will not be examined since it is drawn to non-elected subject matter, i.e. a process of generating the polypeptide of SEQ ID NO: 6. In regard to claim 38, it is noted that claim 38 is partially drawn to the elected invention, i.e. the polynucleotide of SEQ ID NO: 1 and a polynucleotide encoding

the polypeptide of SEQ ID NO: 2. As such, claim 38 will be examined to the extent as it relates to the elected subject matter.

Applicants request that the Examiner consider permitting claims 58-76 to remain in the case. According to Applicants, the polynucleotides of SEQ ID NO: 2 and 4 are not unrelated because they can be used alternatively or together, have identical modes of operation, function and effect, and are structurally highly related.

First, it is noted that it is assumed that Applicant's arguments refer to the polynucleotides of SEQ ID NO: 1 and 3 since SEQ ID NO: 2 and 4 represent polypeptides. In regard to Applicant's arguments, it is noted that claims 58-76 will not be considered for examination purposes. Applicants may elect not to cancel claims 58-76 in response to this Office Action but the Examiner will request cancellation of non-elected claims in response to the Final Action or other appropriate action (37 CFR 1.144). See MPEP § 821.01. Newly added claims 58-76 correspond to Group II as set forth in Paper No. 15, which is drawn to the polynucleotide of SEQ ID NO: 3, host cells, vectors and organisms comprising said polynucleotide, as well as a method of producing the polypeptide of SEQ ID NO: 4. The Examiner does not agree with Applicant's contention that the polynucleotides of SEQ ID NO: 1 and 3 are related and therefore claims drawn to such polynucleotides should be examined together. The polynucleotides of SEQ ID NO: 1 and 3 are distinct products which are structurally and functionally distinct. Furthermore, searching each of these patentably distinct inventions would impose an undue burden on the Office since the searches are not co-extensive. A comprehensive search of each invention would require not only a sequence search for each polynucleotide but also patented and non-patented searches in addition to class/subclass searches.

The requirement is deemed proper and therefore is made FINAL.

Claims 1-6, 8-15, 19, 29-32, 35-36, 58-76 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The specification is objected to since it does not include a "Brief Description of the Drawings" section. See 37 CFR 1.77(b) and MPEP § 608.01(f) for a description of the order in which elements of the application should appear. Appropriate correction is required.

Priority

3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. 119(a)-(d) to GERMANY 10022362.1 filed on 05/08/2000.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 4/8/2002 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

5. The drawings have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDOMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Claim Objections

6. Claim 38 is objected to because it is partially drawn to non-elected inventions, i.e. the polynucleotides of SEQ ID NO: 3 and 5. Applicants are requested to amend the claim and/or

take appropriate action in response to this Office Action. It is noted that if claim 38 is amended to recite " SEQ ID NO: 1" only, the instant claim will be identical to newly added claim 57.

7. Claims 44 and 55 are objected to because of the recitation of "sequence selected from". For clarity, it is suggested that the term "the group consisting of" be inserted immediately after the term "from" in the preamble. Appropriate correction is required.

8. Claim 47 is objected to because of the recitation of "pro- or eukaryotic cells". For clarity, it is suggested that the term be replaced with "prokaryotic or eukaryotic cells". Appropriate correction is required.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 38-44, 56 and 57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 38-44, 56 and 57 as written, do not sufficiently distinguish over nucleic acids or organisms as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page 4, lines 13-24, of specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, Second Paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 38, 40, 42, 44, 51, 55, 56 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claims 38 and 57 are indefinite in the recitation of "(b) sequences encoding polypeptides which comprise the amino acid sequences...., (c) sequences which, owing to the degeneracy of the genetic code encode the same amino acid sequence(s) of SEQ ID NO: 2..." since part (b) and (c) are directed to the same nucleic acid. A polynucleotide which encodes the polypeptide of SEQ ID NO: 2 is the same polynucleotide which due to the degeneracy of the genetic code encodes the polypeptide of SEQ ID NO: 2. It is suggested that part (c) be deleted. Appropriate correction is required.

14. Claim 40 is indefinite in the recitation of "a nucleic acid according to claim 39 wherein the nucleic acid encodes a polypeptide with the amino acid sequence of SEQ ID NO: 2" since it is not further limiting claim 39. Claim 39 is directed to a nucleic acid which encodes a polypeptide comprising the polypeptide of SEQ ID NO: 2. It is suggested that if claim 40 is directed to a nucleic acid which encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2, the claim be amended accordingly. For examination purposes, claim 40 will be considered a duplicate of claim 39. Correction is required.

15. Claim 42 is indefinite in the recitation of "wherein the nucleic acid is a fragment of genomic DNA or cDNA" for the following reasons. According to the specification, the

polypeptide of SEQ ID NO: 2 is a complete tobacco phytoene synthase, therefore the corresponding polynucleotide (SEQ ID NO: 1) represents the complete cDNA of such synthase. As such, it is unclear as to how the claimed polynucleotide can be a fragment of cDNA. For examination purposes, it will be assumed that claim is drawn to the polynucleotide of claim 41 wherein the polynucleotide is cDNA or a fragment of genomic DNA. Correction is required.

16. Claim 44 is indefinite in the recitation of "a nucleic acid according to claim 39....." since it does not further limit claim 39. It is noted that the scope of claim 44 is broader than that of claim 39. Claim 39 is limited to a polynucleotide which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 whereas claim 44 is also drawn to (1) polynucleotides comprising fragments (at least 14 bases) of the polynucleotide of SEQ ID NO: 1, (2) polynucleotides comprising fragments (at least 14 bases) of a polynucleotide encoding the polypeptide of SEQ ID NO: 2, and (3) polynucleotides which hybridize to (1) or (2). Correction is required.

17. Claims 44 and 55 are indefinite in the recitation of "sequences which hybridize with the sequences defined under.." for the following reasons. First, it is unclear as to how sequences can hybridize sequences since hybridization occurs among nucleic acid molecules. Sequences as known in the art, are graphical representations of the order in which nucleotides/amino acids are arranged in a molecule. In addition, is unclear which polynucleotide is being referred to absent a statement of the conditions under which the hybridization reaction is performed. Nucleic acids which will hybridize under some hybridization conditions will not necessarily hybridize under different conditions. For examination purposes, it will be assumed that claim 44 is partially drawn to a polynucleotide which hybridizes under any conditions to (1) a polynucleotide

comprising the nucleotide sequence of SEQ ID NO: 1, (2) a polynucleotide which encodes the polypeptide of SEQ ID NO: 2, or (3) a polynucleotide which comprises at least 14 bases of the polynucleotides of (1) or (2). Similarly, claim 55 will be interpreted as being partially drawn to a process for generating a polypeptide encoded by the polynucleotide as described above. Correction is required.

18. Claims 44 and 55 are indefinite in the recitation of "sequences which are complementary to the sequences.... " for the following reasons. The term "complementary" renders the claim indefinite because it is unclear which "complementary sequences" are encompassed by the claims. Fragments of any size which are complementary to the sequences recited can be considered as "complementary sequences". Applicants have not define the term "complement", as it relates to size, in the specification either. If Applicant's intended "complementary sequence" is the entire complementary sequence, it is suggested that the term "complementary" be replaced with "completely complementary". For examination purposes, the suggested language will be used. Correction is required.

19. Claim 44 is indefinite in the recitation of "(f) sequences which, owing to the degeneracy of the genetic code, encode the same amino acid sequence as the sequences defined under (a) to (c)" for the following reasons. First, part (b) is drawn to a polynucleotide which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2. Since polynucleotides which due to the degeneracy of the genetic code, encode the polypeptide of SEQ ID NO: 2 are equivalent to polynucleotides which encode the polypeptide of SEQ ID NO: 2, it is unclear as to how part (f) relates to part (b). Furthermore, it is unclear as to which are the "amino acid sequences" being referred to in regard to part (c). For examination purposes, it will be assumed

that part (f) refers to "polynucleotides which due to the degeneracy of the genetic code, encode the polypeptide of SEQ ID NO: 2, a polypeptide encoded by a polynucleotide which comprises at least 14 bases of the polynucleotide of SEQ ID NO: 1, or a polypeptide encoded by a polynucleotide which comprises at least 14 bases of a polynucleotide which encodes the polypeptide of SEQ ID NO: 2". Correction is required.

20. Claims 51 and 55 are indefinite in the recitation of "synthase which is encoded by a nucleic acid of SEQ ID NO: 1 including an amino acid sequence of SEQ ID NO: 2" as it is unclear what the meaning of the phrase is. The synthase encoded by the nucleic acid of SEQ ID NO: 1 has the amino acid sequence of SEQ ID NO: 2, therefore it is unclear as to how the term "including an amino acid sequence of SEQ ID NO: 2" further limits the claim. It is suggested that the claim be amended to recite "synthase which is encoded by the polynucleotide of SEQ ID NO: 1" or "wherein said synthase has the amino acid sequence of SEQ ID NO: 2". For examination purposes, the first suggested term will be used. Correction is required.

21. Claim 51 is indefinite in the recitation of "a process ....comprising (a1) or (a2), and (b) as it is unclear and confusing. It is suggested that if the process has two main steps, the claim be amended to recite (a1) and (a2) in one paragraph labeled as (a), followed by step (b). For examination purposes, the format proposed will be used in the interpretation of the claim. Correction is required.

22. Claim 55 is indefinite in the recitation of "(v) sequences which, owing to the degeneracy of the genetic code encode the same amino acid sequence as the sequences defined under (i) or (ii)" for the following reasons. Part (ii) refers to a polynucleotide which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2. Since polynucleotides which due to the

degeneracy of the genetic code, encode the polypeptide of SEQ ID NO: 2 are equivalent to polynucleotides which encode the polypeptide of SEQ ID NO: 2, it is unclear as to how part (v) relates to part (ii). While part (v) could still be examined as referring to part (i) only, for examination purposes, no patentable weight will be given to part (v) since in the absence of a reference to part (ii), part (v) is identical to part (ii). Correction is required.

23. Claim 55 is indefinite in the recitation of "a process for generating ...comprising (a1)...or (a2)...and (b)" as it is unclear and confusing. It is suggested that if the process has two main steps, the claim be amended to recite (a1) and (a2) in one paragraph labeled as (a), followed by step (b). For example, step (a) can be rewritten such that the contents of (a2) are placed first, followed by "or", which can then be followed by the contents of (a1). For examination purposes, the format proposed will be used in the interpretation of the claim. Correction is required.

24. Claim 56 is indefinite in the recitation of "organism selected from plants, parts of plants, protoplasts, plant tissues or plant propagation materials, wherein the organism comprises.....which is encoded by a nucleic acid of SEQ ID NO: 1 including an amino acid sequence of SEQ ID NO: 2 whose bioactivity or expression pattern is modified in comparison with the corresponding endogenous polypeptides" for the following reasons. First, while as known in the art, an organism can be unicellular, such as bacteria, or multicellular, such as plants, it is unclear as to how plant parts, protoplasts, plant tissues or plant propagation materials can be organisms. Furthermore, the term "including an amino acid sequence of SEQ ID NO: 2" is unclear for the reasons discussed above in regard to claims 51 and 55. In addition, the term "whose bioactivity or expression pattern is modified in comparison with the corresponding

endogenous polypeptides" is unclear and confusing. As written, one cannot determine how the term further limits the claim since one cannot establish which bioactivity or expression pattern is modified and which are the corresponding endogenous polypeptides. For examination purposes, the claim will be interpreted as being drawn to an isolated plant, plant parts, protoplasts, plant tissues or plant propagation materials which comprise the polynucleotide of SEQ ID NO: 1. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

25. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

26. Claims 44 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 44 is directed in part to genera of polynucleotides which (1) comprise at least 14 nucleotides of the polynucleotide of SEQ ID NO: 1 or 14 nucleotides of a polynucleotide encoding the polypeptide of SEQ ID NO: 2, or (2) can hybridize under any conditions to (1), the polynucleotide of SEQ ID NO: 1, or a polynucleotide which encodes the polypeptide of SEQ ID NO: 2. Claim 55 is drawn in part to a method of producing polypeptides encoded by (1) or (2). See claim rejections under 35 USC 112, second paragraph for claim interpretation. While the specification discloses the structure and function of the polypeptide of SEQ ID NO: 2 and

the corresponding polynucleotide (SEQ ID NO: 1), the specification is silent in regard to the structure of other polynucleotides as claimed. Furthermore, the specification is silent in regard to which fragments of 14 bases or more are required to encode a polypeptide having phytoene synthase activity. An adequate description of a genus of polynucleotides may be achieved by a recitation of a representative number of polynucleotides defined by their nucleotide sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. The recited structural features of the genera, (1) comprising at least 14 nucleotides of the polynucleotide of SEQ ID NO: 1 or a polynucleotide encoding the polypeptide of SEQ ID NO: 2, or (2) hybridize under any conditions to (1), the polynucleotide of SEQ ID NO: 1, or a polynucleotide encoding the polypeptide of SEQ ID NO: 2, does not constitute a substantial portion of the genera since the remainder of the structure of any polynucleotide having phytoene synthase activity is completely undefined and the specification does not provide the remaining structural features necessary for members of the genera to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicants are referred to the revised guidelines concerning compliance with the written description requirement of 35 USC 112, first paragraph, published in the Official Gazette and also available at the USPTO website.

27. Claims 44 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1 or a polynucleotide encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for (1)

polynucleotides comprising at least 14 nucleotides of the polynucleotide of SEQ ID NO: 1 or at least 14 nucleotides of a polynucleotide encoding the polypeptide of SEQ ID NO: 2, (2) polynucleotides which hybridize under any conditions to (1), the polynucleotide of SEQ ID NO: 1, or a polynucleotide encoding the polypeptide of SEQ ID NO: 2, or (3) methods of producing the polypeptide encoded by (1) or (2). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claims, as described above, is not commensurate with the enablement provided in regard to the large number of polynucleotides encompassed by the claims. As indicated above, while Applicants have disclosed the structure and function of the polypeptide of SEQ ID NO: 2 and its corresponding polynucleotide (SEQ ID NO: 1), the specification does not provide any information as to which are the critical structural elements required in a polynucleotide to encode a phytoene synthase or which 14 nucleotides of the polynucleotide of SEQ ID NO: 1 or a polynucleotide encoding the polypeptide of SEQ ID NO: 2 are required to encode said synthase.

While one could argue that the polynucleotides of the instant claims are enabled since one can isolate these polynucleotides by structural (i.e. sequence) comparison using the

polypeptide/polynucleotide structures disclosed in the instant application or the prior art, the state of the art teaches that sequence comparison alone should not be used to determine function and that small structural changes can drastically change function. Bork (Genome Research, 10:398-400, 2000) teaches protein function is context dependent, and both molecular and cellular aspects must be considered (page 398). Witkowski et al. (Biochemistry 38:11643-11650, 1999) teaches that one amino acid substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. Since the amino acid structure of a polypeptide determines its function, one of skill in the art would require some knowledge or guidance as to how structure is related to function to isolate/make the claimed polynucleotides with the desired function. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to maintain the desired function, and the unpredictability of the prior art in regard to function based on structural homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to isolate/make polynucleotides encoding polypeptides with phytoene synthase activity. Thus,

Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

28. Claims 44 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Fitzmaurice et al. (U.S. Patent No. 5705624; January 1998; cited in the IDS). Fitzmaurice et al. teaches a tobacco polynucleotide encoding a phytoene synthase and the production of such synthase. The polynucleotide of Fitzmaurice et al. (SEQ ID NO: 5, columns 27-30) comprises several fragments of at least 14 nucleotides of the polynucleotide of SEQ ID NO: 1. See attached alignment provided for visualization purposes. As such, the polynucleotide of Fitzmaurice et al. would hybridize to the polynucleotide of SEQ ID NO: 1. Fitzmaurice et al. also teaches the production of the tobacco phytoene synthase by cloning of the tobacco polynucleotide into heterologous systems (column 3, lines 22-33; column 7, line 36-column 10, line 8; Example 2 columns 14-16). Claim 44 is drawn in part to polynucleotides encoding tobacco phytoene synthases comprising at least 14 nucleotides of the polynucleotide of SEQ ID NO: 1 or at least 14 nucleotides of a polynucleotide encoding the polypeptide of SEQ ID NO: 2, or (2) polynucleotides encoding tobacco phytoene synthases which hybridize under any conditions to (1), the polynucleotide of SEQ ID NO: 1, or a polynucleotide encoding the polypeptide of SEQ ID NO: 2. Claim 55 is drawn in part to methods of producing the polypeptides encoded by (1) or (2). Therefore, the teachings of Fitzmaurice et al. as discussed above, anticipate the claims as written.

Allowable Subject Matter

29. Claims 45-46, 48-50, 52-54 appear to be allowable over the prior art of record but are objected to since they depend upon rejected claim 39.

Conclusion

30. No claim is in condition for allowance.

31. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

32. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of

a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 1, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1300~~
1600